

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The use of silver nitrate and platelet fibrin glue in the treatment of anal fistulas

Protocol summary

Study aim

Determining the effect of using silver nitrate and platelet fibrin glue in the treatment of anal fistulas

Design

A non-randomized, uncontrolled, single clinical trial will be conducted in phase 2 on 10 patients.

Settings and conduct

Imam Reza and Qaim Hospital

Participants/Inclusion and exclusion criteria

1. Patients who have a perianal fistula resistant to surgical treatment as diagnosed by a medical specialist;
2. Patients should be over 18 years old;
3. Obtain written consent
4. Patients who, in addition to anal fistula, have other urinary fistulas/active infection/carcinoma in situ/tumor will not be included in the study.

Intervention groups

The intervention group includes individuals with perianal fistula resistant to surgical treatment. In the operating room, 2 ml of 10% silver nitrate will first be injected into their perianal fistula channel. Then 5 ml of platelet-rich fibrin glue will also be injected into the fistula.

Main outcome variables

Reepithelialisation and fistula closure; The disappearance of evidence of discharge and inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191228045924N4**

Registration date: **2023-03-25, 1402/01/05**

Registration timing: **prospective**

Last update: **2023-03-25, 1402/01/05**

Update count: **0**

Registration date

2023-03-25, 1402/01/05

Registrant information

Name

Daryoush Hamidi Alamdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8574

Email address

hamidiad@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The use of silver nitrate and platelet fibrin glue in the treatment of anal fistulas

Public title

Investigating the effect of using silver nitrate and platelet fibrin glue in the treatment of anal fistulas

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have a perianal fistula resistant to surgical treatment as diagnosed by a medical specialist Patients should be over 18 years old Obtain written consent

Exclusion criteria:
Patients who, in addition to anal fistula, have other urinary fistulas/active infection/carcinoma in situ/tumor.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of Mashhad University of Medical Sciences

Street address

Daneshgah street, the central organization of University, Quraishi construction

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2023-03-04, 1401/12/13

Ethics committee reference number

IR.MUMS.REC.1401.405

Health conditions studied

1

Description of health condition studied

Anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

discharge amount

Timepoint

Before the intervention and after the intervention every 24 hours

Method of measurement

By visual observation of the dressing that is placed on the fistula site

2

Description

The duration of recovery, which is the number of days it takes for the discharge from the fistula to stop.

Timepoint

Every 24 hours (every day)

Method of measurement

By visual observation of the dressing that is placed on the fistula site

3

Description

Presence of inflammation and infection

Timepoint

Before the intervention and after the intervention every week for one month

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Reepithelialisation and fistula closure

Timepoint

During the 6-month follow-up period of the patient

Method of measurement

clinical examination

Intervention groups

1

Description

The intervention group includes individuals with perianal fistula resistant to surgical treatment. In the operating room, 2 ml of 10% silver nitrate will first be injected into their perianal fistula channel. Then 5 ml of platelet-rich fibrin glue will also be injected into the fistula.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Amin Dalili

Street address

Iman Reza Hospital, Daneshgah Ave

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2

Recruitment center

Name of recruitment center

Qaim Hospital

Full name of responsible person

Zahra Gholami Moalem

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Ghaem Hospital, Ahmadabad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

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Daneshgah Street, Central Organization of University,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Daryoush Hamidi Alamdari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data related to the project after the unidentifiable people will be shared.

When the data will become available and for how long

Access to data is allowed 6 months after the publication of results.

To whom data/document is available

Our data will be available for university staff and academic institutions

Under which criteria data/document could be used

According to the policies of the journal in which the article will be published, the data will be made available.

From where data/document is obtainable

The corresponding author of the article

What processes are involved for a request to access data/document

The request should be sent by email to the corresponding author and he will respond as soon as possible after reviewing the request.

Comments